Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 14-23 and 25-39 are pending in the application, with claims 23 and 29 being the independent claims. Claims 1-13 and 24 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 29-39 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

New claims 29 - 39 are supported at least by cancelled claims 1-13.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Restriction Election

Applicants thank the Examiner for reconsidering the restriction requirement and examining groups I-III and claims 25-28 that were omitted from the restriction requirement. New claims 29-39 that replace claims 1-13 fall within the restriction groups already being examined and therefore, no further restriction is required.

Information Disclosure Statement

Applicants thank the Examiner for returning an initialed and dated copy of Applicants Form 1449 that was submitted December 7, 2000.

Objection to the Claims

The Examiner objected to claims 4-5 because they allegedly failed to comply with 37 CFR 1.821(d), which requires that reference must be made to a sequence by use of a sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims.

Applicants have cancelled claims 4-5 and have inserted SEQ ID NOS. into independent claims 23 and 29. Therefore, this objection is now moot and should be withdrawn.

Rejections under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejected claims 1-3 and 7-23 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because they allegedly contained subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Specifically, at page 3, the Examiner stated that:

> The claims are drawn to a variety of inducible pathogenesis-related gene promoters of unknown structure, including i) any promoter of any length or sequence which naturally drives the expression of a 21.3 kDa protein in *Asparagus officinalis* upon induction by plant regulators, or ii) any promoter of any length or sequence which is obtained from the *Lillaceae or Amaryllidaceae* families and which naturally drives the expression of proteins equivalent to the 21.3 kDa protein in *Asparagus officinalis,* or iii) any promoter of any length or sequence which naturally drives the expression of proteins substantially homologous to those of i) or ii), or iv) any promoter of any length or sequence which hybridizes under stringent conditions to any one of i), ii) or iii).
>
> In contrast, the specification describes only one inducible pathogenesis-related gene promoter sequence, the 475 base pair AoPRT-L promoter sequence of SEQ ID NO: 1, obtained *from Asparagus officinalis* (sequence listing). The specification additionally describes a salicylic, acid responsive element as comprising the region corresponding to from

> -257 to -133 of the AoPRT- L promoter (pages 40-4 1). The specification does not describe or characterize any other inducible pathogenesis-related gene promoter sequence obtained from *Asparagus officinalis* or from any other species of plant.

Applicants disagree that the specification fails to describe other inducible pathogenesis-related gene promoter sequence obtained from *Asparagus officinalis* or from any other species of plant.

Without acquiescing in the propriety of the rejection and solely in an effort to expedite prosecution, however, Applicants have cancelled claims 1-14. Therefore, the rejection as it applies to claims 1-3 and 7-14 is moot. New claim 29(i) incorporates the limitation of previous claim 4. Claim 4 was not previously rejected for lack of written description and therefore, at a minimum, this embodiment of claim 29 is allowable.

The new claims provide structure in the claims by relying on SEQ ID NO:1. (Claim 29, first member of the group (i)) and therefore the basis for rejection of claims 1-3 and 7-14 is not applicable to new claims 29-39. Additionally, Applicants have amended claims 15-23 such that they are dependent either directly or indirectly on claims reciting SEQ ID NO:1. Therefore the rejection for lack of structure as it applies to claims 15-23 is overcome.

Recitation of SEQ ID NO:1 in the claims provides adequate structure for that which is being claimed. Additionally, Applicants have provided "function" which is associated with the "core structure" of the molecule being claimed, thereby fully meeting the written description requirements. For example, as set forth in 29 ii), the structure of SEQ ID NO:1 must provide the function of being a "molecule [that] acts as an inducible promoter, whose expression is a) induced by salicylic acid (SA) and by BTH (benzo (1,2,3) thiadiazole-7-carbonic acid S methyl ester), b) is not systemically activated by pathogen infection and c) exhibits minimal developmentally-regulated expression."

As acknowledged above by the Examiner, Applicants have provided at least two-members of the genus being claimed, i.e. 1) the 475 base pair AoPRT-L promoter sequence of SEQ ID NO:1 and 2) the salicylic acid responsive element comprising the region from -257 (actually -247) to -133 of the AoPRT-L promoter. Additionally, in Example 13, in order to construct an AoPRT-L promoter having higher expression, the region -247 bp up to -133 was amplified and placed twice in front of a -247 bp AoPRT-L promoter. Therefore, Applicants have provided at least three species of any genus encompassed by the claims. This should be considered a representative number of species to describe the genus. If the Examiner disagrees, she is respectfully requested to provide a number considered to be a "representative number" and further provide the basis for providing the specific number.

Based on all of the above, one of skill in the art would have recognized that Applicants were in possession of the claimed invention as of the filing date of the application. Applicants have provided both a core structure (i.e. SEQ ID NO:1) and function associated with that structure. Applicants have also provided at least three members of the claimed genus. Therefore, this rejection is overcome and should be withdrawn.

Rejections under 35 U.S.C. § 112, First Paragraph (Enablement)

The Examiner rejected claims 1-3 and 7-23 under 35 U.S.C. 112, first paragraph, alleging that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

The Examiner noted at page 5 that the specification:

> . . . while being enabling for a salicylic acid and BTH inducible AoPRT-L promoter of SEQ ID NO:1 obtained from *Asparagus officinalis,* a

> salicylic acid and BTH inducible promoter element region corresponding to from -257 to -133 of the AoPRT-L promoter of SEQ ID NO:1, and a promoter construct comprising the AoPRT-L promoter of SEQ ID NO:1 operably linked to a synthetic sequence encoding a LhG4 transactivator and a pOP transactivator target promoter sequence, does not reasonably provide enablement for other nonexemplified promoter sequences obtained from *Asparagus officinalis* or from other sources. . . .
>
> * * *
>
> The specification discloses the isolation from *Asparagus officinalis* of a promoter that controls the expression of a gene encoding a 21.3 kDa protein (AoPRT-L) that has homology to proteins encoded by the thaumatin-like PR5 gene family (pages 30-32). The specification also discloses the construction of an AoPRT-L promoter-GUS chimeric gene and the analysis of its expression in transgenic tobacco, *Brassica napus and Zea mays* plants transformed therewith, including the induction of GUS expression by salicylic acid and BTH (pages 32-40). The specification additionally discloses the identification of a salicylic acid responsive element of the AoPRT-L promoter, between -247 bp and the putative CAT and TATA boxes, and the construction of a chimeric promoter (AoPRT-Lx3) comprising the AoPRT-L promoter and two copies of the region corresponding to from -257 to -133 of the AoPRT-L promoter (pages 40-41). The specification indicates that tobacco plants transformed with the AoPRT-Lx3 chimeric promoter-GUS chimeric gene exhibit significantly greater GUS activity upon induction by salicylic acid or BTH than do plants transformed with the AoPRT-L promoter-GUS chimeric gene (page 42). The specification further discloses the construction of a construct (pGB24) comprising the AoPRT-L promoter operably linked to a synthetic sequence encoding an LhG4 transactivator, a pOP transactivator target promoter sequence, and GUS reporter gene sequence. The specification indicates that tobacco and *Brassica napus* plants transformed with pGB24 exhibit significantly greater GUS activity upon induction by salicylic acid or BTH than do plants transformed with the AoPRT-L promoter-GUS chimeric gene (pages 42-43). The specification does not disclose the structure or function of any other inducible pathogenesis-related gene promoter obtained from *Asparagus officinalis* or from other sources.

Applicants disagree that the specification failed to reasonably provide enablement for "other nonexemplified promoter sequences obtained from *Asparagus officinalis* or from other sources." In any event the rejection is moot as applied to claims 1-3 and 7-11, which have been cancelled.

The Examiner has clearly acknowledged above that the invention is enabled for many different embodiments of the claimed invention. Those embodiments are

incorporated as limitations into new claims 29-39. Additionally, previously rejected claims 14-23 contain similar limitations.

The specification provides ample guidance such that one of skill in the art could have practiced the claimed invention at the time of filing without undue experimentation. For example, beginning at page 18, the specification provides guidance for the use of probes under stringent conditions to identify a promoter having the same specificity as the exemplified promoter. More particularly, the specification (and Figure 6) clearly describes sequences that are important for induceability, thereby providing guidance for identification of additional suitable promoters that fall within the claim.

Additionally, the quantity of experimentation necessary to obtain additional embodiments of the claimed invention is low, because multiple species can be easily screened using appropriate probes and no more than repetitive procedures. While such experimentation may be repetitive, it certainly is not "undue." A large amount of experimentation is permitted for enablement as long as it is not undue.

The Examiner states at page 7 that:

> Sequences homologous to a promoter sequence also cannot predictably be assumed to have promoter activity. This unpredictability originates in the mechanics of promoter function, which requires the presence of particular nucleotides, in the sequence to directly mediate promoter function. As a consequence, it is unpredictable whether sequence variants of SEQ ID NO:1 would have inducible or basal promoter function, because it is unpredictable whether any sequence variant would possess all the particular nucleotides necessary to mediate inducible or basal promoter function. . . .

While one may not be able to predict with "absolute certainty" whether a sequence homologous to a promoter sequence may have promoter activity, this should not be the basis for a lack of enablement rejection. One of skill in the art can follow the guidance provided in the specification (*see* Examples 1-2) and can with confidence determine whether or whether not a homologous sequence has promoter activity. Thus,

there is no lack of predictability in being able to screen and determine promoter activity of a homologous sequence. In any event, lack of predictability is merely one factor that can be considered for a determination of lack of enablement.

Other factors argue against undue experimentation. These factors include adequate guidance provided in the specification, breadth of claims and the high level of expertise of the skilled artisan in this area. Guidance in the specification has been discussed above. Additionally, both the new and amended claims have a reasonable breadth because they are ultimately dependent on SEQ ID NO:1. Therefore, based on all of the above, this rejection of the claims should be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

At page 8 of the office action the Examiner rejected claims 1-3, 5-6, 9-11 and 13, and claims dependent thereon, under 35 U.S.C §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection

The Examiner rejected claims 1 and 2 because of the recitations "plant regulators and "BTH" respectively. Claims 1 and 2 have been cancelled. New claim 29 that replaces claim 1 does not recite "plant regulators" and claim 2 provides the meaning for the acronym "BTH." Therefore, these aspects of the rejection are now moot.

Claim 3 was rejected for the recitation of "thaumatin-like PR-5 protein." This rejection is moot in view of the cancellation of claim 3 and new claim 29 that refers to a specific SEQ ID NO.

Claims 5, 6 and 9 were rejected because of the recitation of "SA", as an acronym. The rejection is moot in view of the cancellation of claims 5, 6 and 9 and in view of the claim language of claim 29. Claim 29 provides the meaning of "SA."

Claims 10 and 11 were rejected because of the recitation "amplification system." The rejection is moot in view of the cancellation of claims 10 and 11.

Claim 13 was rejected for the recitation of "preferably LhG4" and "preferably pOP910." Claim 13 has been cancelled and therefore this aspect of the rejection is now moot.

Based on all of the above, the rejection under 35 USC §112, second paragraph should be withdrawn.

Rejection under 35 U.S.C. § 102(b)

At page 9, the Examiner rejected claims 1-3, 14-16 and 18-23 under 35 U.S.C. §102(b) as being anticipated by Hennig et al. (Plant J. 1993 Sep;4(3):481-93). Applicants respectfully traverse this rejection.

Without acquiescing in the propriety of the rejection and solely in an effort to expedite prosecution, Applicants have cancelled claims 1-3. Claims 14-16 and 18-23 have been amended or are dependent on the new or amended claims and are not anticipated by the cited art. The new and amended claims contain limitations that rely on SEQ ID NO:1. Therefore, Hennig does not anticipate any of the claims.

Based on all of the above the rejection is either rendered moot or is overcome and should be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the

outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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